REMARKS

The Office action dated November 14, 2008 is acknowledged. Claims 1-82 are pending in the instant application. According to the Office action, claims 1-6, 11-23 and 42-46 are rejected and claims 7-10, 24-41 and 47-82 have been withdrawn. By the present Office Action response, claims 1, 6, 13, 42 and 43 have been amended and claims 83-90 have been added. Support for claims 83-90 may be found throughout the present specification, such as at paragraphs [000017] and [000030]. Claims 13, 42 and 43 have been amended for non-substantive clarification purposes. The amendments to claims 1 and 6 are discussed below. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1-6, 11-23 and 42-46 under 35 U.S.C. 112, second paragraph

Claims 1-6, 11-23 and 42-46 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that the claims recite "film-shaped preparation" but that it cannot be ascertained what is meant by "film-shaped."

Claims 1 and 6 have been amended to clarify this matter. In particular, the claims have been amended to recite "said preparation being in the form of a film or of a wafer" rather than being "film-shaped." Reference is made to paragraphs [00007] – [000012] of the present specification for support.

It is also submitted that claim 1 has been amended to clarify the "drying step"

wherein the step includes "drying said coating compound." Reference is made to paragraphs [000053] of the present specification for support.

Claim 6 has also been amended to clarify the term "at least one gas-forming component" as "two or more gas-forming components." Reference is made to paragraph [000020] of the present specification for support of this limitation. In addition, claim 6 has been amended to recite that the components are each homogenously distributed within the preparation, support for which may be found at Examples 1 and 2 of the present specification. As set forth in paragraph [000053] therein, the gas-forming components (3, 4) are stirred into the polymer solution until the mass is homogenous. Therefore, the gas-forming components (3, 4) become distributed homogenously.

Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-6, 11-23 & 42-46 under 35 U.S.C. 102(b)

Claims 1-6, 11-23 and 42-46 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Publication No. 2001/0006677 (McGinity, et al.). The Examiner states that McGinity, et al. teach each and every limitation of the aforementioned claims. In particular, the Examiner states that McGinity, et al. disclose effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration. The formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes, that the films may be single layer or multilayer films and that the films comprise a water soluble or swellable film binder and active ingredient, a plasticizer and an effervescent couple which produces a gas (i.e., carbon dioxide or oxygen) when in water. The Examiner further states that the

effervescent components include sodium bicarbonate and sodium carbonate and acids such as citric acid and maleic acid. Still further, the Examiner states that film will dissolve/disintegrate at a controlled rate when exposed to a water containing solution and that the thickness of the film ranges from 0.1 mm to 2 mm. As a single layer, the Examiner concludes that the film will be the product of a single extrusion and when multi-layered film is involved, the different layer can be co-extruded in an extruder equipped with two die slots and then laminated together. Alternatively, the Examiner concludes that the different layers can be separately extruded one on the other. Regarding flavorings, the Examiner states that those may include peppermint oil which comprises menthol and that the components are mixed together encompassing suspending the components in a suspending agent.

Regarding the process of the presently claimed invention, the Examiner concludes that in the case of a single layer, when the hot melt forms a film, the surface it extruded upon becomes dry and in the case of the two layers, the first layer which the second layer is extruded upon may be considered the substrate and becomes dry when the two layers form a film.

Therefore, the Examiner concludes that McGinity, et al. disclose every limitation of the presently claimed invention.

The Applicant respectfully disagrees with the Examiner's assessment discussed above. It is respectfully submitted that McGinity, et al. fail to disclose each and every limitation of the presently claimed invention. For example, at page 4 of the Office action, the Examiner states that "in the case of a single layer, when the hot melt forms a film, the

surface it is extruded upon becomes dry." This statement relates to the previous provision of claim 1 of "drying said support" which is amended herein to recite "drying said coating compound."

The Applicants also submit that the statement "in the case of a single layer, when the hot melt forms a film, the surface it is extruded upon becomes dry" alleges that the surface must have been wet or moist because otherwise it could not subsequently "become dry." However, the Applicants submit that the prior art reference fails to teach or disclose any wet or moist surfaces. The hot-melt production methods described by McGinity, et al. do not include any drying steps for drying a coating mass that was spread on a support.

Referring to present claim 6 (amended herewith), the claim requires two or more gas-forming components each being homogenously distributed within the preparation. In contrast, McGinity, et al. teach the presence of an "effervescent couple" comprising an acidic agent combined with an alkaline agent which is included in "effervescent granules" and further comprising effervescent granule binder (see paragraph [0071] of McGinity, et al.). It respectfully submitted that McGinity, et al. clearly fail to teach two or more gas-forming components each being homogenously distributed within the preparation, as set forth in present claim 6 as amended herewith.

The Applicants further submit that McGinity, et al. fail to each any polymers selected from the group consisting of copolymer of methyl vinyl ether and maleic acid, pullulan and acrylates, as set forth in new claim 88.

In view of the above, it is submitted that McGinity, et al. clearly fail to teach or

otherwise disclose each and every limitation of the present invention as set forth in the present claims and therefore the reference fails to anticipate the present invention. Withdrawal of this rejection is respectfully requested.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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